

AMENDMENTS TO THE CLAIMS

1. (Currently Amended) A sterile pharmaceutical composition of propofol ~~stored in a container, the composition comprising a container which includes a closure and a composition in the container, the composition in the container comprising propofol and less than about 10% by weight solvent for propofol, said container in which the composition is stored comprising a closure for said container,~~ wherein ~~said the~~ closure is inert to propofol.

2. (Currently Amended) The ~~composition of claim 1~~ sterile pharmaceutical composition in a container according to claim 1, wherein ~~said the~~ composition further ~~comprises comprising~~ an aqueous phase and protein.

3. (Currently Amended) The sterile pharmaceutical composition in a container according to claim of claim 2, wherein the protein is albumin.

4. (Currently Amended) The sterile pharmaceutical composition in a container according to claim of claim 3, wherein the albumin is present in an amount of from about 0.01% to about 5% by weight of the composition.

5. (Currently Amended) The sterile pharmaceutical composition in a container according to claim of claim 2, wherein the aqueous phase comprises water ~~of for~~ injection and a pH modifier.

6. (Currently Amended) The sterile pharmaceutical composition in a container according to claim of claim 2, wherein the composition comprises a tonicity agent.

7. (Currently Amended) The sterile pharmaceutical composition in a container according to claim of claim 3, wherein the pH modifier is sodium hydroxide.

8. (Currently Amended) The sterile pharmaceutical composition in a container according to claim of claim 6, wherein the tonicity agent is glycerin.

9. (Currently Amended) The sterile pharmaceutical composition in a container according to claim 2, wherein the composition further comprises a surfactant.

10. (Currently Amended) The sterile pharmaceutical composition in a container according to claim 1, wherein the composition further comprises a solvent for propofol.

11. (Currently Amended) The sterile pharmaceutical composition in a container according to claim 10 wherein the solvent is a water-immiscible solvent.

12. (Currently Amended) The sterile pharmaceutical composition in a container according to claim 11, wherein the water-immiscible solvent is selected from the group consisting of soybean, safflower, cottonseed, corn, coconut, sunflower, arachis, castor sesame, orange, limonene or olive oil, an ester of a medium or long-chain fatty acid, a chemically modified or manufactured palmitate, glycerol ester or polyoxyl, hydrogenated castor oil, a marine oil, fractionated oils, and mixtures thereof.

13. (Currently Amended) The sterile pharmaceutical composition in a container according to claim 12, wherein the water-immiscible solvent is soybean oil.

14. (Currently Amended) The sterile pharmaceutical composition in a container according to claim 10, wherein the solvent is selected from the group consisting of chloroform, methylene chloride, ethyl acetate, ethanol, tetrahydrofuran, dioxane, acetonitrile, acetone, dimethyl sulfoxide, dimethyl formamide, methyl pyrrolidinone, C1-C20 alcohols, C2-C20 esters, C3-C20 ketones, polyethylene glycols, aliphatic hydrocarbons, aromatic hydrocarbons, halogenated hydrocarbons and combinations thereof.

15. (Currently Amended) The sterile pharmaceutical composition in a container according to claim 9, wherein the surfactant is selected from the group consisting of phosphatides, synthetic phospholipids, natural phospholipids, lecithins, ethoxylated ethers and esters, tocopherol polyethylene glycol stearate, polypropylene-polyethylene block copolymers, polyvinyl pyrrolidone, and polyvinylalcohol and combinations thereof.

16. (Currently Amended) The sterile pharmaceutical composition in a container according to claim 15, wherein the surfactant is selected from the group consisting of egg phosphatides, soya phosphatides, egg lecithins, soya lecithins, and compositions thereof.

17. (Currently Amended) The sterile pharmaceutical composition in a container according to claim 16, wherein the surfactant is egg lecithin.

18. (Currently Amended) The sterile pharmaceutical composition in a container according to claim 1, wherein the closure is coated with a material inert to propofol.

19. (Currently Amended) The sterile pharmaceutical composition in a container according to claim 1, wherein the closure is comprised of a material that is itself inert to propofol.

20. (Currently Amended) The sterile pharmaceutical composition in a container according to claim 19, wherein the material inert to propofol is selected from the group consisting of a fluoropolymer, silicone, and mixtures thereof.

21. (Currently Amended) The sterile pharmaceutical composition in a container according to claim 19, wherein the material is selected from the group consisting of bromobutyl rubber, chlorobutyl rubber, a fluoropolymer, silicone, non-rubber, metal, and mixtures thereof.

22. (Currently Amended) The sterile pharmaceutical composition in a container according to claim 19, wherein the material is selected from the group consisting of bromobutyl rubber, chlorobutyl rubber, a fluoropolymer, silicone, and mixtures thereof.

23. (Currently Amended) The sterile pharmaceutical composition in a container according to claim 1, wherein the closure comprises bromobutyl rubber coated with a fluoropolymer.

24. (Currently Amended) The sterile pharmaceutical composition in a container according to claim 1, wherein the closure comprises siliconized bromobutyl rubber.

25. (Currently Amended) The sterile pharmaceutical composition in a container according to claim 1, wherein the closure comprises a non-rubber, or metal.

26. (Currently Amended) The sterile pharmaceutical composition in a container according to claim 1, wherein the closure comprises chlorobutyl rubber coated with a fluoropolymer.

27. (Currently Amended) The sterile pharmaceutical composition in a container according to claim 1, wherein the closure comprises siliconized chlorobutyl rubber.

28. (Currently Amended) The sterile pharmaceutical composition in a container according to claim 1, wherein the composition comprises propofol in an amount of from about 0.1% to about 10% by weight of the composition, soybean oil in an amount of from about 0.5% to about 6% by weight of the composition, egg lecithin in an amount of from about 0.1% to about 5% by weight of the composition and human serum albumin in an amount of from about 0.1% to about 5% of the composition.

29. (Currently Amended) A sterile pharmaceutical composition of propofol ~~stored~~ in a container comprising a container which includes a closure and an oil-in-water emulsion for parenteral administration of propofol in the container.

~~said~~ the composition comprising an oil phase comprising propofol and less than about 10% by weight solvent for propofol and an aqueous phase comprising water for injection, and the composition further comprising a stabilizing layer for the oil phase, the stabilizing layer comprising a surfactant and a protein,

~~said container in which the composition is stored comprising a closure for the container,~~ wherein the closure is inert to propofol.

30. (Currently Amended) The sterile pharmaceutical composition in a container according to claim 1, wherein the protein is selected from the group consisting of

albumins, globulins, immunoglobulins, lipoproteins, caseins, insulins, hemoglobins, lysozymes, alpha-2-macroglobulin, fibronectins, vitronectins, fibrinogens, lipases, peptides, enzymes, antibodies and combinations thereof.

31. (Currently Amended) The sterile pharmaceutical composition in a container according to claim ~~of~~claim 29, wherein the surfactant is selected from the group consisting of phosphatides, synthetic phospholipids natural phospholipids, lecithins, ethoxylated ethers and esters, tocopherol polyethylene glycol stearate, polypropylene-polyethylene block copolymers, polyvinyl pyrrolidone, and polyvinylalcohol.

32. (Currently Amended) The sterile pharmaceutical composition in a container according to claim ~~of~~claim 29, wherein the oil phase is propofol neat.

33. (Currently Amended) The sterile pharmaceutical composition in a container according to claim ~~of~~claim 29, wherein the surfactant is lecithin and the protein is albumin.

34. (Currently Amended) The sterile pharmaceutical composition in a container according to claim ~~of~~claim 29, wherein the oil phase includes a solvent, and wherein the solvent is selected from the group consisting of soybean, safflower, cottonseed, corn, coconut, sunflower, arachis, castor sesame, orange, limonene or olive oil, an ester of a medium or long-chain fatty acid, a chemically modified or manufactured palmitate, glycerol ester or polyoxyl, hydrogenated castor oil, a marine oil, fractionated oils, and mixtures thereof, chloroform, methylene chloride, ethyl acetate, ethanol, tetrahydrofuran, dioxane, acetonitrile, acetone, dimethyl sulfoxide, dimethyl formamide, methyl pyrrolidinone, C1-C20 alcohols, C2-C20 esters, C3-C20 ketones, polyethylene glycols, aliphatic hydrocarbons, aromatic hydrocarbons, halogenated hydrocarbons and combinations thereof.

35. (Currently Amended) The sterile pharmaceutical composition in a container according to claim ~~of~~claim 34, wherein the solvent is soybean oil.

36. (Currently Amended) The sterile pharmaceutical composition in a container according to claim ~~of claim~~ 35, wherein the soybean oil is present in an amount of from about 0.5% to about 6% by weight of the composition.

37. (Currently Amended) The sterile pharmaceutical composition in a container according to claim ~~of claim~~ 33, wherein the egg lecithin is present in the composition in an amount of from about 0.1% to about 5% by weight of the composition and the albumin is present in the composition in an amount of from about 0.01% to about 5% by weight of the composition.

38. (Currently Amended) The sterile pharmaceutical composition in a container according to claim ~~of claim~~ 37, wherein the oil phase includes soybean oil.

39. (Currently Amended) The sterile pharmaceutical composition in a container according to claim ~~of claim~~ 38, wherein the soybean oil is present in an amount of from about 0.5% to about 6% by weight of the composition.

40. (Currently Amended) The sterile pharmaceutical composition in a container according to claim ~~of claim~~ 38, wherein the soybean oil is present in the composition in an amount of from about 0.5% to about 3% by weight of the composition.

41. (Currently Amended) The sterile pharmaceutical composition in a container according to claim ~~of claim~~ 31 comprising:

- a) about 1% to 2% by weight of propofol,
- b) 3-6% by weight of soybean oil,
- c) 0.2-1.0% by weight of egg lecithin,
- d) about 2.25% by weight of glycerin,
- e) sodium hydroxide,
- f) water to 100%, and
- g) pH between 5.0-8.5.

42. (Currently Amended) The sterile pharmaceutical composition in a container according to claim 29, wherein the closure is treated with a material inert to propofol.

43. (Currently Amended) The sterile pharmaceutical composition in a container according to claim 29, wherein the closure comprises a material that is itself inert to propofol.

44. (Currently Amended) The sterile pharmaceutical composition in a container according to claim 42, wherein the material inert to propofol is selected from the group consisting of a fluoropolymer, silicone, and mixtures thereof.

45. (Currently Amended) The sterile pharmaceutical composition in a container according to claim 43, wherein the material is selected from the group consisting of bromobutyl rubber, chlorobutyl rubber, a fluoropolymer, silicone, non-rubber, metal, and mixtures thereof.

46. (Currently Amended) The sterile pharmaceutical composition in a container according to claim 46, wherein the material is selected from the group consisting of bromobutyl rubber, chlorobutyl rubber, a fluoropolymer, silicone, and mixtures thereof.

47. (Currently Amended) The sterile pharmaceutical composition in a container according to claim 29, wherein the closure comprises bromobutyl rubber coated with a fluoropolymer.

48. (Currently Amended) The sterile pharmaceutical composition in a container according to claim 29, wherein the closure comprises siliconized bromobutyl rubber.

49. (Currently Amended) The sterile pharmaceutical composition in a container according to claim 29, wherein the closure comprises non-rubber, or metal.

50. (Currently Amended) The sterile pharmaceutical composition in a container according to claim 29, wherein the closure comprises chlorobutyl rubber coated with a fluoropolymer.

51. (Currently Amended) The sterile pharmaceutical composition in a container according to claim 29, wherein the closure comprises siliconized chlorobutyl rubber.

52. (Currently Amended) A sterile, injectable pharmaceutical composition stored in a container comprising a container which includes a closure and a composition in the container, the composition comprising:

a) microdroplets having a mean size of from about 20 nanometers to about 1000 nanometers, the microdroplets comprising a sphere of propofol surrounded by a stabilizing layer comprising a phospholipid and devoid of oils capable of supporting bacterial growth; and

b) a pharmaceutically acceptable injectable carrier,
~~the container in which the composition is stored comprising a closure for the container,~~ wherein the closure is inert to propofol.

53. (Currently Amended) The sterile, injectable pharmaceutical composition in a container according to claim 52, wherein the composition further comprises albumin.

54. (Currently Amended) The sterile, injectable pharmaceutical composition in a container according to claim 52, wherein the stabilizing layer includes albumin.

55. (Currently Amended) The sterile pharmaceutical composition sterile, injectable pharmaceutical composition in a container according to claim 52, wherein the closure is coated with a material inert to propofol.

56. (Currently Amended) The sterile pharmaceutical composition sterile, injectable pharmaceutical composition in a container according to claim 52, wherein the closure comprises a material that is itself inert to propofol.

57. (Currently Amended) The sterile pharmaceutical composition sterile, injectable pharmaceutical composition in a container according to claim of ~~claim~~ 55, wherein the material inert to propofol is selected from the group consisting of a fluoropolymer, silicone, and mixtures thereof.

58. (Currently Amended) The sterile pharmaceutical composition sterile, injectable pharmaceutical composition in a container according to claim of ~~claim~~ 56, wherein the material is selected from the group consisting of bromobutyl rubber, chlorobutyl rubber, a fluoropolymer, silicone, non-rubber, metal, and mixtures thereof.

59. (Currently Amended) The sterile pharmaceutical sterile, injectable pharmaceutical composition in a container according to claim of ~~claim~~ 55, wherein the material is selected from the group consisting of bromobutyl rubber, chlorobutyl rubber, a fluoropolymer, silicone, and mixtures thereof.

60. (Currently Amended) The sterile pharmaceutical composition sterile, injectable pharmaceutical composition in a container according to claim of ~~claim~~ 52, wherein the closure comprises bromobutyl rubber coated with a fluoropolymer.

61. (Currently Amended) The sterile pharmaceutical composition sterile, injectable pharmaceutical composition in a container according to claim of ~~claim~~ 52, wherein the closure comprises siliconized bromobutyl rubber.

62. (Currently Amended) The sterile pharmaceutical composition sterile, injectable pharmaceutical composition in a container according to claim of claim 52, wherein the closure comprises a non-rubber, or metal.

63. (Currently Amended) The sterile pharmaceutical composition sterile, injectable pharmaceutical composition in a container according to claim of ~~claim~~ 52, wherein the closure comprises chlorobutyl rubber coated with a fluoropolymer.

64. (Currently Amended) The ~~sterile pharmaceutical composition~~ sterile, injectable pharmaceutical composition in a container according to claim of claim 52, wherein the closure comprises siliconized chlorobutyl rubber.

Claims 65-67. (Canceled)

This listing of claims replaces all prior versions, and listings, of claims in the application.